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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Agency for Toxic Substances
and Disease Registry

Memorandum

Date July 1, 1994

From Director, Division of Health Assessment and Consultation

Subject Site Review and Update (SRU) Guidance

To DHAC and State Health Assessors

The current Site Review and Update (SRU) guidance is attached. The guidance has been revised and updated based on two years of experience conducting SRUs. The primary change in the guidance is that under certain, specific conditions a health hazard category for a site can be revised. This guidance is meant to provide health assessors with direction when they encounter certain site conditions. The guidance is intended to be used as flexible guidelines for conducting SRUs, not as rigid requirements. If you have any questions about this guidance, please see your supervisor or Lisa Hayes in the Superfund Site Assessment Branch.

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Attachment

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GUIDANCE FOR
SITE REVIEW and UPDATE

The purpose of a Site Review and Update (SRU) is to review a site's current conditions and determine whether further assessment or actions by the Agency for Toxic Substances and Disease Registry (ATSDR) are needed. An SRU will ensure that sites with the greatest potential for affecting public health get a thorough evaluation.

An SRU is not an addendum to a public health assessment (PHA). Instead, it reports on the current status of a site before, during, or after the completion of a public health assessment or other site public health evaluation document. Documents that should be reviewed include any public health assessments, health consultations, and health advisories or similar site public health evaluation documents previously prepared for the site, and other summary documents, such as Records of Decision, Feasibility Studies or data summaries. Usually, the evaluation of data for an SRU is limited and the evaluation of extensive data is generally not desirable for the preparation of an SRU. If extensive data need evaluation, a PHA or health consultation is usually recommended. Decision criteria for assisting health assessors in determining when additional evaluation is necessary are provided in Attachment 1.

An SRU should describe what has changed since the public health assessment, public health advisory or health consultation (or other site public health evaluations) was issued (if one has already been conducted) and should emphasize public health actions already completed. A site visit is a required part of an SRU, and the site must have been visited within 1 to 2 years before finalization of the SRU. A visit to the site that occurred previously during this time period for another reason (i.e., consultation, emergency response, public meeting, etc.) may serve as the site visit for an SRU. Authors should use professional judgement to determine the necessity of performing an official site visit, as done for a public health assessment (with representatives of ATSDR, the state, the Environmental Protection Agency [EPA], and the site owner present). The ATSDR Regional Office must be contacted during and involved in the development of an SRU.

An SRU should emphasize the following (also see format section below):

1. how conditions have changed at the site since the previous site public health evaluation (including the results of past and current ATSDR, EPA, and state activities and actions at the site), if applicable

2. a description of new data that highlights the need for further assessment or actions or the lack of need for further assessment

or actions,

3. current ATSDR/State concerns/issues and community concerns about the site, and

4. issues or situations that need further evaluation.

Recommendations for further assessment must include one or more of the following:

1. a public health advisory,

2. a public health assessment,

3. a health consultation,

4. no further assessment (including a supporting reason, such as no identifiable public health hazards because remedial actions have removed current and future health concerns or public health actions have addressed past exposures).

In addition, an SRU will contain previous ATSDR documents' recommendations that are still valid and outstanding, new recommendations based on current conditions, and a Health Activities Recommendation Panel (HARP) statement (if applicable) and a Public Health Action Plan (PHAP) (if applicable). Under certain circumstances, an SRU may contain a PHAP even when it is not reviewed by HARP.

See Attachment 2 for examples of SRUs.

An SRU that recommends a follow-up public health assessment requires a completed Site Ranking Scheme. In addition, authors will make a recommendation on whether an SRU should receive a HARP review using the attached HARP decision tree (Attachment 3).

When the author determines that a health consultation is the appropriate followup to an SRU, and the information is available to prepare that consultation, the SRU can be converted to a health consultation. This decision should be discussed with the section chief/technical project officer (TPO) to determine whether workplan commitments can be met and whether resources would be better used by preparing a health consultation rather than an SRU.

The flow procedures for an SRU are as follows:

1. The author writes the SRU, makes a recommendation to the section chief/TPO about HARP review, completes the SRU abstraction form (Attachment 4), and provides the SRU, the SRU abstraction form, and the HARP recommendation to the section chief/TPO for review.

2. The section chief/TPO reviews the document. The section

chief/TPO decides whether a HARP evaluation is necessary based on the author's recommendation (made by using the HARP decision tree) and the information provided in the SRU and completes the HARP form (Attachment 5). Then the section chief/TPO returns the SRU to the author.

3. The author revises the document as necessary and inserts the appropriate HARP statement. If a HARP evaluation is indicated, the author provides a copy of the SRU to HARP (through normal procedures) for review.

4. After the HARP statement has been inserted into the document, the SRU and the Site Ranking Scheme (required if the SRU recommends a PHA) will be submitted by the author to the section chief/TPO for the Branch consistency review. In addition, all SRUs that are presented to HARP must include a PHAP. (PHAPs should be approved according to current policy.) At this point, a draft of the SRU can be shared with the Regional Representative, EPA, and the State using the same procedures as in the Quality Assurance Segment Team's report for informal review of draft public health assessments. After this review, the author or TPO will submit the SRU to the Records and Information Management Branch (RIMB) of ATSDR's Division of Health Assessment and Consultation for distribution.

5. RIMB makes the necessary copies and distributes the SRU following the same distribution procedures used for an initial release PHA. RIMB also updates the tracking system and enters the abstracted information into HazDat.

6. Regional Representatives and representatives of EPA and the states will have the opportunity to officially review the SRU at this time. If comments are not received within 30 days of the date on the cover of the SRU, the SRU is considered to be final. The SRU will be revised and reprinted only if comments result in substantial changes (i.e., to the conclusions and recommendations). If comments do not result in substantial changes, the SRU will not be revised, and the comments will become a part of the official site file. A formal written response or conference call is required to respond to EPA comments that are unclear or not addressed.

7. For information about public distribution of SRUs, see Attachment 6.

SRU FORMAT

An SRU should be four to five pages and should be developed using the following format.

SUMMARY OF BACKGROUND AND HISTORY

- Brief description of type of site, location and history (includes activities and actions by ATSDR, EPA, and states, such as consultations, site remediation, health outcome data analysis, and community health education)
- Brief description of the pathways and contaminants of concern in previous site public health evaluations, e.g., public health assessments, health consultations, and public health advisories (if applicable)
- Brief description of past public health hazards and community concerns
- Outline of past conclusion category and recommendations (if applicable)

PUBLIC HEALTH IMPLICATIONS (OPTIONAL)

- Toxicological evaluation of past exposures only

CURRENT CONDITIONS OF SITE

- Date of recent site visit and current site-visit observations
- An indication of how conditions at the site have changed since previous site public health evaluation(s). If conclusions made in the previous site public health evaluation(s) were incorrect or incomplete, explain
- A brief description of new data that highlights the need either to perform further assessment or not, or to perform further actions or not (may include a list of contaminants of concern as defined in the summary documents reviewed)

CURRENT ISSUES

- ATSDR/state public health concerns
  - Past concerns which still exist and newly identified concerns
- Community health concerns
  - Past concerns which still exist and newly identified concerns

CONCLUSIONS

- Health hazard category, if applicable; see Attachment 1
- Were old conclusions valid? (if applicable)
- Were recommendations in the previous site public health evaluation document(s) followed? (if applicable)
- What is the need for further assessment of and/or action at the site?

RECOMMENDATIONS

- Still-valid recommendations from previous site public health evaluation document(s)
- New recommendations based upon updated conditions
- Recommendation for further assessment (full public health assessment, consultation, etc.) and the urgency of the followup (i.e., should followup be immediate, when data become available, or when resources permit?)
- HARP statement and PHAP (when appropriate)

DOCUMENTS REVIEWED

PREPARERS OF REPORT

Attachment 1

DECISION CRITERIA FOR PREPARING A SITE REVIEW AND UPDATE (SRU)

PURPOSE: To provide additional guidance to health assessors who prepare Site Review and Updates (SRU).

BACKGROUND INFORMATION:

An SRU will often be the last document about a site that ATSDR will prepare. Because of this, it may be appropriate to change a site's health hazard category in the SRU. Generally, a site's hazard category can be changed in an SRU only when no further ATSDR or state public health assessment or consultation is recommended.

According to the ATSDR Public Health Assessment Guidance Manual (PHAGM) 1992, the following are among the important factors that must be weighed in an analysis to determine the appropriate health hazard category:

- **presence of completed or potential exposure pathways;**
- on-site and off-site environmental contamination concentrations;
- potential for multiple-source exposures;
- contaminant interactions;
- presence of sensitive subpopulations;
- opportunity for acute or chronic exposures;
- nature of toxic effects associated with site contaminants;
- community-specific health outcome data (HOD);
- **community health concerns (CHC);**
- **presence of physical hazards.**

The health assessor reviews site conditions during an SRU to determine 1) if exposure above health guidelines is occurring ; 2) if significant physical hazards exist; and 3) if community health concerns exist. These are the most critical factors involved in selecting a health hazard category. The other factors are related to these three significant factors and do not need to be evaluated if the three significant factors do not exist or have been addressed. Hence, using the logic stated in the PHAGM, a health hazard category can be assigned to the site for past, present and/or future site conditions.

The following list includes samples of scenarios that would permit a change of the health hazard category and would provide general guidance on preparing SRUs.

SCENARIOS

1. NO CHC/NO EXPOSURE ABOVE HEALTH GUIDELINES

SITUATION: Exposure above health guidelines is not likely, there are no CHC, and the SRU recommends no further ATSDR (or state) assessment.

ACTION: **The hazard category can be changed.** This change should usually be from indeterminate (or potential) public health hazard to no apparent public health hazard.

2. NO EXPOSURE ABOVE HEALTH GUIDELINES/CHC ADDRESSED BY ACTION(S) TAKEN OR PLANNED

SITUATION: Exposure above health guidelines is not likely, and actions have been performed or are planned to address CHC.

ACTION: In most cases, a hazard category of "No Apparent Public Health Hazard" can be assigned to the site. However, if the action planned to address CHC is an analysis of HOD, then the hazard category should not be changed in the SRU. **The SRU should recommend that a health consultation be performed after the HOD are analyzed.** Use the HARP Decision Tree to determine whether the SRU should be sent to HARP.

3. NO EXPOSURE/CHC NOT ADDRESSED BY ACTIONS(S) TAKEN OR PLANNED

SITUATION: Exposure above health guidelines is not likely, and CHC exist, particularly related to adverse health outcomes and/or exposure to site contaminants.

ACTION: If data and information are currently available to address the CHC, then **the SRU should recommend a health consultation, the evaluation of CHC should be performed in the SRU, or the SRU should be converted to a health consultation (with management approval). If the evaluation is included in the SRU, then the health hazard category can be changed in the SRU in accordance with PHAGM. Otherwise, the health hazard category will be changed in the health consultation.**

If the SRU recommends obtaining data or information, the **SRU should recommend a health consultation to analyze the data and information** <u>when available.</u> Use the HARP Decision Tree to determine whether the SRU should be sent to HARP.

4. NO CHC (OR CONCERNS HAVE BEEN ADDRESSED)/PAST EXPOSURE

SITUATION: Has past exposure been evaluated under current PHA procedures? **Yes or no.**

ACTION: IF YES - **The SRU and the previous PHA should be evaluated per the HARP decision tree to determine whether HARP referral is needed.** The health hazard category should be correct in the previous PHA.

If NO - When there are limited completed exposure pathways (in most cases, two or fewer) the following actions may be considered:

1) **A toxicological evaluation may be conducted in the SRU.** The evaluation should include an analysis of HOD or reasons why it would not be appropriate to include it. **If the evaluation is included in the SRU, then the health hazard category can be changed in the SRU in accordance with PHAGM.** Use the HARP Decision Tree to determine whether the SRU should be sent to HARP; **or**

2) **The SRU should recommend a health consultation to perform the toxicological evaluation, or**

3) **The SRU should be changed to a health consultation (with management approval). If a health consultation is performed, then the health hazard category will be changed in the health consultation.**

IF NO - With multiple or extensive exposure pathways, **the SRU should recommend a PHA. The PHA goes to HARP.**

5. NO CHC (OR CONCERNS HAVE BEEN ADDRESSED)/PRESENT OR FUTURE EXPOSURE

SITUATION: Has present or future exposure been evaluated under current PHA procedures? **Yes or no.**

ACTION: IF YES - **The SRU and the previous PHA should be evaluated per the HARP Decision Tree to determine whether HARP referral is needed. The health hazard category should be correct in the previous PHA.**

IF NO - With limited completed exposure pathways (in most cases, two or fewer), **the SRU should recommend a health consultation to perform the**

FACTORS FOR KEYSTONE LANDFILL TASK FORCE CONSIDERATION

Public Health Assessment Document and Public Health Assessment Process

- When we call the *Public Health Assessment* document *FINAL*, we do not mean that the public health assessment process is final. New information, whether the information comes from EPA, state health and environmental agencies, or THE COMMUNITY, is reviewed and considered.

- One major goal of health assessors, regional representatives, and technical project officers is to accurately represent community concerns at Health Activities Recommendation Panel (HARP) sessions.

- HARP thoroughly investigates all possible actions that can be taken at a site before determinations are made. That can take time, especially if the requested action is new to ATSDR or if the action is indicated, but resources are not readily available.

- If no actions are indicated, as determined by HARP, health assessors continue to look at new information, including new or continuing community concerns. That information is usually addressed in a follow-up document called a *Site Review and Update*.

What Will Be Helpful to Your Community?

- Would Fact Sheets be helpful? If so, what issues would you want addressed and how often?

- Is continued participation in Task Force Meetings helpful? If so, do you want the same people to participate or would you prefer to have participants vary? Keep in mind, that the people now attending are most familiar with your concerns and with the processes in place to address those concerns.

- What other processes would be helpful?

For technical information concerning the public health assessment process, please contact

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For community involvement information, please call

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